

ABOUT JESSE

Jesse practices out of Harris Bricken's Portland office and co-chairs the Litigation Practice Group. His litigation practice has an international component as well as focusing representing cannabis business in a variety of disputes. These often include contract, secured transactions, partnership disputes, and disputes between members of closely-held companies.

Jesse also represents marijuana licensees in Oregon in administrative proceedings commenced by the Oregon Liquor Control Commission. Jesse frequently speaks and writes on these issues and has made national media appearances, including the New York Times. Jesse also authors a weekly column for his firm's award-winning Canna Law Blog.



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BRIEF OVERVIEW OF HEMP'S LEGAL STATUS

Feb. 7, 2014

Pursuant to the enactment of the 2014 Farm Bill, hemp can be lawfully cultivated for research purposes only.

Dec. 20, 2018

Hemp is legalized along with its commercial production.

BEFORE Feb. 7, 2014

Hemp is a controlled substance under federal law.



THE 2018 FARM BILL

• It legalized "hemp," which is defined as:

the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

Section 297A(1) of the 2018 Farm Bill (emphasis added)

Hemp is now an agricultural commodity.







THE 2018 FARM BILL

 USDA tasked with regulating the "production" of hemp. This is done by the Agricultural Marketing Services arm of the USDA.

- Six key provisions:
 - Licensing requirements;
 - Recordkeeping requirements;
 - Procedures for testing the THC level concentration in the hemp plant;
 - Procedures for disposing of non-compliant hemp (i.e., hemp that exceeds acceptable THC threshold);
 - · Compliance provisions; and
 - Procedures for handling violations.

THE 2018 FARM BILL

- State and Tribal Plans.
 - USDA regulations are a floor not a ceiling.
 - Choice to (1) operate under 2014 or 2018 Farm Bill or (2) opt out.
 - Oregon
 - Regulates more than production
 - Imposes additional requirements, such as export and import





DEA

- Although the DEA is not mentioned in the 2018 Farm Bill; the DEA established its own rules re the legality of "intermediary hemp"
 - Exploits the regulatory gap in the 2018 Farm Bill;
 and
 - Ignores the definition of "Hemp" includes the legalization of the processing of hemp to maintain authority over cannabis.
 - Who is concerned about this? Primarily processors.
- The hemp industry sued in response
 - Exploits the regulatory gap in the 2018 Farm Bill;
 and
 - Ignores the definition of "Hemp" includes the legalization of the processing of hemp to maintain authority over cannabis.



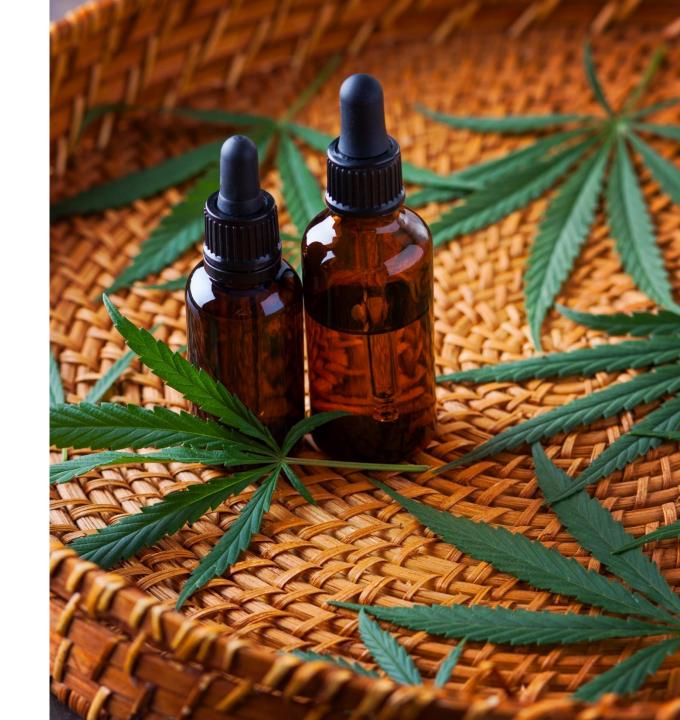


REGULATORY FRAMEWORK OF HEMP CBD PRODUCTS

FDA POSITION ON HEMP CBD PRODUCTS

- Although the 2018 Farm Bill legalized hemp, its derivatives, extracts and cannabinoids, the new law expressly preserved the authority of the FDA to regulate hemp-derived products.
- The hemp-CBD industry is still waiting for any kind of formal guidance from the FDA.





REGULATORY FRAMEWORK OF HEMP CBD PRODUCTS FDA Authority

The FDA regulates the manufacture, sale and marketing of:

- 1. Foods;
- 2. Dietary supplements;
- 3. Cosmetics;
- 4. Tobacco products; and
- 5. Drugs + drug devices





FDA REGULATORY FRAMEWORK OF HEMP CBD PRODUCTS POSITION ON CBD IN FOODS AND DIETARY SUPPLEMENTS

- The FDA takes the position that introducing into commerce any conventional foods or dietary supplements containing Hemp CBD is unlawful.
 - Reasoning: "The Drug Exclusion Rule"

Because *Epidiolex* (purified form of CBD) was:

- (1) approved as a drug; and
- (2) substantial clinical trials studying CBD as a new drug ingredient were made public *prior* to the marketing of any food or dietary supplements containing CBD
- → CBD cannot also be treated as a food ingredient or a dietary supplement.



REGULATORY FRAMEWORK OF HEMP CBD PRODUCTS

Position on CBD in Cosmetics

- The FDA seems to not take issue with Hemp CBD cosmetics, provided these products are:
 - 1. Not adulterated; and
 - 2. Not mislabeled.
- Category of products currently presenting the least amount of risks.







REGULATORY FRAMEWORK OF HEMP CBD PRODUCTS

Position on CBD in Smokable Products

- Historically, the FDA has limited its regulatory authority to smokable products containing tobacco and nicotine.
- Because the majority of Hemp CBD smokable products found on the market are free of tobacco and nicotine, it is unclear whether the FDA will regulate these products.
- Smokable hemp has been a bright spot in otherwise generally dismal marketplace for producers.

REGULATORY FRAMEWORK OF HEMP CBD PRODUCTS

ENFORCEMENT ACTIONS

- Warning letters are not without force.
- An FDA warning letter can lead to further and more significant headaches, including litigation, major fines and penalties and other claims, including:
 - 1. state law consumer protection claims based on prohibiting unfair and deceptive trade practices;
 - claims under the Lanham Act for false and misleading advertising;
 - 3. consumer and shareholder actions relating to CBD (e.g., Curaleaf Inc.); and
 - 4. personal injury claims.





PATCHWORK OF REGULATIONS

- Despite the FDA's current position on Hemp CBD products, states have adopted their own approaches to regulating these products that are not necessarily consistent with the FDA's current position.
- For example, some states:
 - 1. Allow the manufacture and sale of all Hemp CBD products, including foods and dietary supplements.
 - 2. Strictly prohibit the production and/or sale of any such products except for "medical treatment."
 - 3. Ban some Hemp CBD products, typically foods, but seem to take no issue with the sale of other products.
 - 4. Some states ban "smokable" hemp (e.g. Indiana).



IMPACT OF REGULATORY PATCHWORK ON HEMP CBD COMPANIES

- This patchwork of state-by-state regulations forces manufacturers and distributors selling Hemp CBD products in e-commerce to:
 - to limit sales to jurisdictions in which products are deemed lawful; and
 - follow a variety of regulations in each state where products are sold, including but not limited to:
 - 1. Licensing and permits;
 - 2. Product Registration; and
 - 3. Labeling.





LABELING REQUIREMENTS

- Although it is virtually impossible to be in full compliance with all state-level labeling requirements imposed on Hemp CBD products, some labeling requirements have become standard across states where the sale and marketing of these products is allowed:
 - 1. Statement of identity;
 - 2. Net weight content;
 - 3. Nutrition / Supplement facts / List of ingredients;
 - 4. Concentration of each marketed cannabinoids;
 - 5. Directions on intended use;
 - 6. Manufacturer or distributor's information:
 - 7. Warnings;
 - 8. FDA statements;
 - 9. QR code; and
 - 10. No medical claims.





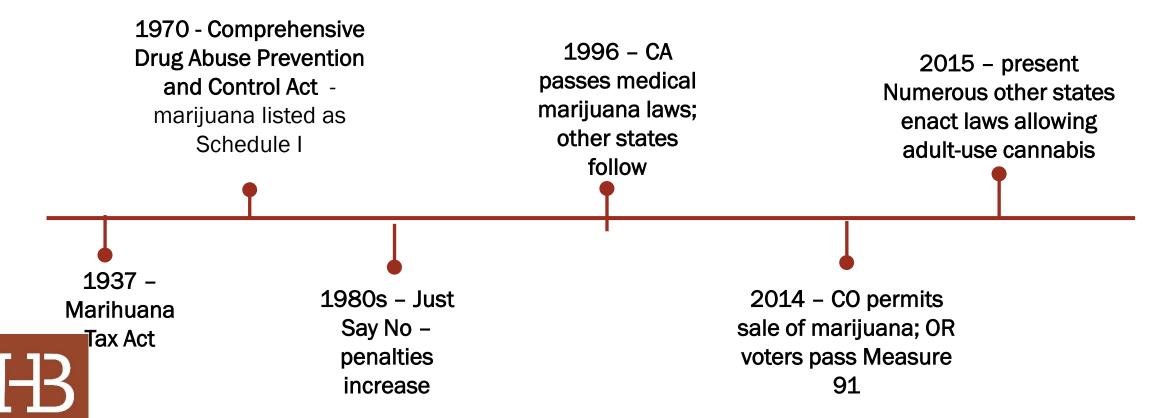
April 2021 – Idaho lawmakers agree to bill allowing the production, processing, transportation and research of hemp.

- Allows commercial production to begin in 2022
- Requires the plant's total THC content, including THC-A, to be at or below .3%
- Requires hemp transporters to submit to law enforcement searches
- Idaho intends to submit a plan to the USDA for approval





BRIEF OVERVIEW OF MARIJUANA'S LEGAL STATUS



Where are we today?

Legalization is happening at the local level across the country

- Sixteen states and the District of Columbia has legalized marijuana for adult recreational use
- Earlier this month, New York and Virginia legalized adult-use cannabis.
- Approximately 40% of Americans live in jurisdictions where some form of marijuana use is legal.
- 2020 Election Cannabis on-the-ballot successful across the country (Arizona, Mississippi, Montana, New Jersey, South Dakota, Washington D.C.)
- Even decriminalization of psychedelics (e.g. psilocybin) is happening (Ann Arbor, MI, Denver, CO, California (measure introduced), Oregon (Measure 110),



Significant issues resulting from federal prohibition

- No bankruptcy protection.
- No federal lawsuits.
- IRC 280E.
- Access to banking.
- Raising capital is difficult.
- Risk of federal law enforcement stepping in.





What will Biden do?

- Democratic platform supported decriminalization and de-scheduling or re-scheduling marijuana on the Controlled Substances Act.
- But Biden has stopped short of any kind of endorsement of legalizing marijuana.
- Other fish to fry.
- Merrick Garland, Attorney General Why the DOJ still matters.
 - The Cole Memorandum
 - Americans for Safe Access et al. v. the Drug Enforcement Administration
 - Wide latitude in terms of enforcement

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What about Congress?

- Schumer: "If I become majority leader, I put it on the floor, and my guess, it'll pass [the MORE Act]. It'll get Democratic and Republican votes."
- Legalization a supposed priority of Congress under Democratic controlled Senate.
- But strong opposition anticipated from Minority Leader Mitch McConnell



The Marijuana Opportunity & Expungement Act (the MORE Act)

- Passed by the House on December 4, 2020
- Would end federal marijuana prohibition and the criminalization of cannabis by descheduling marijuana from the Controlled Substances Act.
- But despite the news coverage, the MORE Act does not mean marijuana becomes legal nationwide.
- The MORE Act does not preempt state law.
- If MORE ACT passes, federal agents will not track or arrest marijuana traffickers, but state police certainly may.
- Would result in a patchwork of state legality.
- Would not affect the FDA's position under the Food, Drug and Cosmetic Act that cannabis and cannabis-derived compounds are drugs that require FDA approval before they may be added to foods and beverages, sold as dietary supplements, or advertised for therapeutic purposes.

The SAFE Banking Act

- First introduced in the fall of 2019.
- Passed in the House three times, but never got out of the Senate Banking Committee.
- Reintroduced in March 2021.
- The SAFE Banking Act aims to create a safe harbor for banks and credit unions so they cannot be held liable or subject to federal forfeiture action for providing financial services to a cannabisrelated business.
- Would allow banks and financial institutions to legally do business with the cannabis industry without fear of arrest or prosecution.
- Access to bank a significant issue for marijuana businesses operating on an all-cash basis.
- OLCC data similarly indicates Portland dispensaries were robbed, burglarized, or looted over 100 times in 2020.
- Budtender fatally shot in December 2020 in a robbery of a Portland dispensary.
- Ultimately, the SAFE Banking Act is "bridge" legislation, not a full-scale end of prohibition.

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